

REMARKS

Traversal of the Examiner's Rejection of Claims 1 to 6 and 8
Under the Written Description Requirement of Section 112, First Paragraph

The Examiner rejected Claims 1 to 6 and 8 under the written description requirement of Section 112, first paragraph, because, according to the Examiner, the descriptive portion of the application does not adequately support such claims for reasons of record. The Examiner cites Berkner, et al., WO 92/15686 as an example of an adequate description, because Berkner, et al. identified the modified serine residue as Ser 344.

The Examiner's rejection of Claims 2 and 3 have been rendered moot by the cancellation of such claims. Applicants will treat this as a rejection of Claims 1, 4 – 6 and 8.

With respect to Claims 1, 4 to 6, and 8, applicant notes that it is unnecessary to describe and claim the serine residues this way because their positions were well known by the time the patent application was filed. Furthermore, WO 92/15686 is predominantly directed to inhibiting Factor VII by deleting or replacing the active serine residue by means of recombinant genetics. In merely one paragraph modification with chemicals such as sulfonyl fluorides is disclosed. Unlike the present application, there are no examples demonstrating the successful inhibition of blood coagulating factors by chemical modification.

Stated another way, WO 92/15686 is a useful tool for demonstrating how the present application by way of its examples provides adequate evidence of possession of the presently claimed subject matter. WO 92/15686

makes but a prophetic mention of the presently claimed subject matter. Actual evidence of blood factor inhibition by chemical derivatization is demonstrated in the Examples of the present application. Applicants, and not WO 92/15686, provide the level of evidence adequate to demonstrate possession of blood factor inhibition by chemical derivatization for purposes of the written description requirement.

Given the above, applicant requests respectfully the withdrawal of the Examiner's rejection of Claims 1 to 6 and 8 under the written description requirement of Section 112, first paragraph.

Traversal of Examiner's Section 102(b)
Rejection of Claims 1 and 6 as Being Anticipated by WO 92/15686

The Examiner continues to reject Claims 1 and 6 under Section 102(b) as being anticipated by WO 92/15686 for reasons of record. According to the Examiner, Examples 1 to 3 of the '686 publication disclose a substance formed by anydridizing the active serine residue of blood coagulation Factor VII. The Examiner cites page 7, line 11, as disclosing the chemical derivatization of the Factor VII catalytic center (containing a serine residue) with a sulfonyl fluoride.

WO 92/15686 is primarily directed to inhibiting Factor VII by deleting or replacing the active serine residue by means of recombinant genetics. In merely one paragraph modification with chemicals such as sulfonyl fluorides is disclosed. Unlike the present application, there are no examples demonstrating the successful inhibition of Factor VII by chemical modification.

While WO 92/15686 discloses that Ser 344 of Factor VII was replaced with Ala by means of recombinant genetics, this publication provides inadequate teaching of a method by which Factor VII may be successfully inhibited by chemical modification. Accordingly, WO 92/15686 is not competent as prior art against the present application for the scope of the subject matter that is presently claimed.

Given the above, applicant requests respectfully the withdrawal of the Examiner's rejection of Claims 1 and 6 as being anticipated by the '686 publication.

Traversal of Examiner's Section 102(b)
Rejection of Claims 1 to 5 and 8 as Being Anticipated by U.S. Patent No. 5,679,639

The Examiner continues to reject Claims 1, 4, 5 and 8 under Section 102(b) as being anticipated by U.S. Patent No. 5,679,639 for reasons of record. According to the Examiner, the '639 patent discloses factor IX and factor X molecules which have been modified so that they now serve as inhibitors of factor IX and factor X activity, respectively.

Applicants must continue to submit respectfully that the Examiner is in error. The Examiner identifies page 13, lines 20-30 of the '639 patent as the relevant description. However, while several chemical derivatizations are disclosed, no mention is made of anhydridizing a serine hydroxyl group. Chemical derivatization is disclosed as being a method by which the conservative substitution of an amino acid residue with an analogue is performed. However, there is no mention in the '639 patent of blood coagulation inhibitors produced by the conservative substitution of serine residues with anhydridized serine.

The '639 patent does not contemplate blood coagulation inhibitors formed by anhydridizing serine residues. Claim 1, on which Claims 4 and 5 depend, and Claim 8, which include the recitations thereof, recite that the substance comprises an anhydridized active site serine. Because nowhere in the '639 patent is there any disclosure of a compound which comprises an anhydridized active site serine, the '639 patent thus does not teach each element of the rejected claims and, therefore, does not anticipate such claims.

The '639 patent does not even remotely suggest anhydridizing active serine residues. Claims 1, 4, 5 and 8 are, therefore, also not obvious in view of the '639 patent.

Given the above, applicant requests respectfully the withdrawal of the Examiner's rejection of Claims 1, 4, 5, and 8 as anticipated by the '639 patent.

Traversal of Examiner's Section 102(e)
Rejection of Claim 7 as Being Anticipated by Suzuki et al.

The Examiner rejected Claim 7 under Section 102(e) as being anticipated by Suzuki et al., U.S. Patent No. 5,939,304. The Examiner notes that the presently claimed method steps are disclosed by the '304 patent but observes that there is a common inventor and that the rejection might be overcome with a proper showing under Rule 131 or by a Rule 132 Declaration showing that the subject matter was derived from the common inventor. *J. Biol. Chem.*, 259: 2306-10 (1984).

The Examiner's courtesies are greatly appreciated. Applicants reserve the right to submit an appropriate Declaration after the other outstanding issues in the present application are resolved.

Traversal of Examiner's Section 102(a) Rejection of Claims 1, 4 to 6 and 8 as Being Anticipated by the Nogami et al. Journal Article

Claims 1, 4 to 6 and 8 were rejected under 35 U.S.C. §102(a) as being anticipated by Nogami, et al. We note that Nogami, et al. was published on October 22, 1999, which is after the June 14, 1999 priority date of the present application. Accordingly, Nogami et al. is not properly prior art against the present application.

Given the above, applicants requests respectfully the withdrawal of the Examiner's rejection of Claims 1, 4 to 6 and 8 as being anticipated by the Nogami et al. journal article.

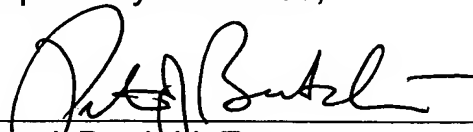
Conclusion

For the reasons expressed above, applicants request respectfully that the Examiner reconsider and withdraw the rejections under §§102 and 112.

In view of the foregoing amendment and remarks, an early and favorable action is requested respectfully.

Respectfully submitted,

April 5, 2005



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